APPENDIX B

Nontechnical description of protocol

We plan to deliver genetic information ("DNA") to the tumor cells of melanoma patients. Because it is difficult to deliver DNA directly to cells, we plan to use replication defective viruses ("vectors") that efficiently deliver the DNA to living cells. These vectors cause the patients tumor cells to produce an important protein called gamma interferon (γ-IFN). γ-IFN is an important protein because it causes the tumor cell to be brought to the attention of the patient's immune system. It is hoped that the resultant expression of γ-IFN from the tumor cells will dramatically improve immune responses that combat human cancer.

Tumor cells from human melanomas removed surgically from the patient will be grown in the laboratory under sterile conditions. The cell culture will then be placed in contact with the vector that contains the DNA coding for γ-IFN . After a process which removes tumor cells which have not taken up the γ-IFN DNA, the cells will be tested for sterility, irradiated with X-rays so that they can no longer grow, and the tumor cells expressing γ-IFN will be re-injected into the same patient. The study will determine if the approach is safe, if the patient's clinical condition is improved, and whether immune responses against the tumor have been improved.